

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

Hon. Robert Kugler

Civil No. 1:19-md-2875-RBK-JS

This Document Relates to:

All Actions

**PLAINTIFFS' RESPONSE IN OPPOSITION TO AUROBINDO PHARMA LTD.'S
MOTION FOR PROTECTIVE ORDER REGARDING THE DEPOSITION OF DR. A
RAM MOHAN RAO AND PRODUCTION OF HIS CUSTODIAL FILE**

Plaintiffs, by and through their undersigned counsel, hereby submit this Response in Opposition to Aurobindo Pharma Ltd.'s Motion for Protective Order to preclude the deposition of its Chief Quality Officer Dr. A Ram Mohan Rao and the production of his custodial file and in support thereof states as follows:

I. FACTUAL BACKGROUND

As the Court is aware, this issue arose because Aurobindo's productions to date have been massively deficient, and Aurobindo Pharma Ltd. has produced very few documents. As Aurobindo laid out in its brief, Plaintiffs requested that Dr. Rao be included as a custodian at the beginning of this litigation. [[Dkt. 1036](#), p. 3]. At that time, Aurobindo refused to include Dr. Rao as a custodian, on the sole basis that Dr. Rao was employed by an Indian entity of Aurobindo that had not been officially served at that time. *Id.* Accordingly, Dr. Rao has been on Aurobindo's radar as an important potential custodian since the very beginning of this litigation, as Aurobindo itself admits

in its brief. Despite this, Aurobindo now inexplicably claims it did not have notice of this desired custodian and that Plaintiffs' request is untimely. These arguments are red herrings and do nothing to allow Aurobindo to meet its burden of proof in establishing that Dr. Rao is an apex witness or that he is entitled to protection under the Apex doctrine.

At the February Case Management Conference, the Court approved Plaintiffs' request to require Aurobindo produce additional custodial files to cover the following topics:

1. Contracting with Lantech;
2. Conducting due diligence on Lantech in terms of quality and cGMP compliance;
3. Providing Lantech with specifications for the use, recovery, recycling, and cleaning of the solvents used in the manufacture of Aurobindo's VCDs; and
4. Investigating any cGMP, contamination, or NDMA issues with Lantech.

Based on all the information available to Plaintiffs, Dr. Rao appears to be the best person to address topic 4 on this list.

On March 4, 2021, Aurobindo's counsel provided the three names listed below. After searching through the documents, Plaintiffs were able to find very little on these three individuals, but particularly Mr. Kasava Reddy and Mr. Nagaraju (as detailed below). Accordingly, Plaintiffs requested additional information as to why Aurobindo selected each custodian and which topics from Plaintiffs' agenda letter are covered by each, and for what time period. This request was made first via e-mail and again in Plaintiffs' agenda letter for the March Discovery Conference. [*See* [Dkt. 1011](#), p. 22]. To date, Plaintiffs have not received a response. Plaintiffs therefore requested at the March Discovery Conference that the Court compel Aurobindo to provide Plaintiffs with this information now to ensure the proper custodians have been selected.

Plaintiffs included in their March agenda letter what little information they could find on each custodian:

- **Mr. Kesava Reddy (VP Outsourcing)** - His name appears in only 2 documents produced to date, and it is therefore impossible to determine what he does or whether he is relevant.
- **Mr. Ashok Reddy (Assistant General Manager of Corporate QA)** - Plaintiffs agree to this custodian, so long as this is the same person being referenced in APL-MDL 2875-0031674-APL-MDL 2875-0031767 at page 1 of the document.
- **Mr. Nagaraju (full name not provided by Aurobindo) (Deputy Manager of Quality Assurance)** - Plaintiffs are concerned that this is not a relevant custodian. In APL-MDL 2875-0026486-APL, Mr. Nagaraju is referred to as the Quality Assistance person for Unit XVI, which to Plaintiffs' knowledge did not make valsartan.

[[Dkt. 1011](#), p. 22.].

In light of the above, Plaintiffs have little confidence that the custodians selected by Aurobindo are either the right people and/or are insufficient to cover the issues Plaintiffs requested. Aurobindo also has yet to propose another custodian who does cover the Court-approved topics as to Lantech. Based upon the documents available from Aurobindo Pharma, Ltd., Plaintiffs proposed the addition of Dr. A. Ram Mohan Rao, Aurobindo's Chief Quality Officer.

Contrary to Aurobindo's contention, Dr. Rao is not an apex witness. However, even if the Court determined that he did qualify as an apex witness, he does not deserve protection under the doctrine, due to his direct involvement with many critical issues in this case.

In his capacity as Chief Quality Officer, Dr. Rao has direct involvement with issues central to this case. Below are just a few examples illustrating his direct involvement with valsartan, quality issues, and the resulting contamination and recall:

- [REDACTED]
[REDACTED] See Exhibit A, Auro-MDL 2875-0107164.
- [REDACTED]
[REDACTED]. See Exhibit B, Auro-MDL 2875-0080757
- [REDACTED]
[REDACTED]. See Exhibit C, Auro-MDL 2875-0100584; see also Exhibit D, Auro-MDL 2875-0087828; Exhibit E, Auro-MDL 2875-0107754; Exhibit F, Auro-MDL 2875-0107477;

- [REDACTED]
[REDACTED]
[REDACTED]. Exhibit G, APL-MDL 2875-0094925.
- [REDACTED]
[REDACTED]. Exhibit H, APL-MDL 2875-0148638.
- [REDACTED]
[REDACTED]. See Exhibit I, APL-MDL 2875-0103466; see also Exhibit J, APL-MDL 2875-0081660; Exhibit K, APL-MDL 2875-0037862.
- [REDACTED]
[REDACTED]. Exhibit L, Auro-MDL 2875-0021295.

Aurobindo's assertion that Dr. Rao is somehow protected by the Apex doctrine is belied even by the small production of documents Aurobindo has made to date. Dr. Rao has unique knowledge concerning all of the items above, which bear on both liability and causation.

Further, while counsel for Aurobindo mentioned during the last status conference with the Court that it would also be moving for a protective order regarding the deposition of Dr. Venkata Kota, Aurobindo decided to bring this Motion only as to Dr. Rao. For that reason, Plaintiffs ask that the Court overrule any objection to the deposition of Vinkata Kota under the apex doctrine and permit that deposition to proceed.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 26 permits "discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Under what has been referred to as the "apex doctrine," Courts have the ability to prohibit the deposition of a high-level executive where the executive has no firsthand personal knowledge of the events in dispute. See *Younes v. 7-Eleven, Inc.*, 2015 WL 12844446, at

*2–3 (D.N.J. Aug. 19, 2015) (denying motion to depose 7–Eleven's President and CEO and its former Executive VP and COO who had no personal and unique knowledge that could not be obtained from other witnesses); *Ciarrocchi v. Unum Group*, 2009 WL 10676631, at *4 (D.N.J. Aug. 27, 2009) (denying motions for depositions of two current high level executives who had no unique knowledge regarding plaintiff's claim which could not be obtained from lower level employees who plaintiff declined to depose). *But see In re Tylenol (Acetaminophen) Mktg. Sales Practices & Prods. Liab. Litig.*, 2014 WL 3035791, at *3 (denying motion to quash the subpoenaed deposition of defendant's former President who “was actively involved in the decision making regarding...marketing and product development.”); *Otsuka Pharm. Co.*, 2008 WL 4424812, at *5 (denying defendant's motion for a protective order because the defendant's CEO had unique knowledge that other witnesses were unable to provide); *Engage Healthcare Commc'ns, LLC v. Intellisphere, LLC*, No. 12CV00787FLWLHG, 2017 WL 9481235, at *6 (D.N.J. Nov. 1, 2017), report and recommendation adopted, No. CV 12-787 (FLW)(LHG), 2017 WL 6539242 (D.N.J. Dec. 21, 2017).

III. ARGUMENT

Notably, Aurobindo does not argue that Dr. Rao is not a relevant witness to this case. Ostensibly recognizing that relevance is not a winning strategy for barring Plaintiffs from obtaining Dr. Rao's custodial file or from deposing Dr. Rao, Aurobindo instead contends that Dr. Rao is an apex witness, and in the alternative, that discovery from Dr. Rao would be duplicative and overly burdensome. First, Aurobindo itself admits in its brief that it has known since the beginning of this litigation that Plaintiffs intended to have Dr. Rao included as a custodian. Second, Dr. Rao is not an apex witness for the reasons articulated below. Finally, Dr. Rao is in possession of unique information on Valsartan and its contamination which cannot be obtained from other

witnesses, and Aurobindo has not nearly met the “heavy burden” imposed by the Third Circuit on motions for protective order precluding depositions.

A. Dr. Rao Is Not An Apex Witness

Aurobindo relies on *United States ex rel. Donald R. Galmines, et al. v. Novartis Pharmaceuticals Corp.*, No. 06-3213, 2015 WL 4973626 (E.D. Pa. Aug. 20, 2015) in arguing that Dr. Rao is an apex witness, and even goes as far as to say “[t]he case at bar is almost identical to *Galmines*.” [Dkt. 1036, p. 6.]. This is untrue. The deponent sought in *Galmines* was the company’s CEO; Dr. Rao is not Aurobindo’s CEO. More importantly, the party seeking discovery from the CEO in *Galmines* relied on nothing more than a PowerPoint slide that the CEO had allegedly reviewed and a single email, and they failed to connect either of these pieces of evidence to the nexus of the case, per the court. *Id* at *2.

This situation is entirely different. As described above, Dr. Rao was directly involved with FDA inspections, the recall of Aurobindo’s valsartan, responses to the FDA and telephone calls about the recall. Perhaps more importantly, the contamination of Aurobindo’s valsartan was, at its core, a quality problem. Dr. Rao is the head of the department that triggered the massive public health crisis that resulted in the instant MDL.

Further, Plaintiffs here have presented much more than a PowerPoint slide and a single email, demonstrating that Dr. Rao was deeply connected to the issues at the heart of the claims and defenses in this case. *See* Exhibits A-L. In fact, Aurobindo has not cited a single case holding that a Chief Quality Officer is an apex witness. Accordingly, the discovery from Dr. Rao—both the production of his custodial file and his deposition—should be ordered.

B. Even If Dr. Rao Was An Apex Witness, He Was Directly Involved With Issues Critical To This Case, And He Possesses Unique Knowledge About Facts Which Bear On Liability And Causation

Even if the Court determined that Dr. Rao is an apex witness, he is not entitled to protection under the doctrine, because he was directly involved with the issues in this case. Far from being the executive who is far removed from issues, Dr. Rao was directly involved with the major quality issues that are at the center of this case.

An apex witness that “was actively involved in the decision making” regarding issues at the center of a case is not shielded from discovery or depositions. *See In re Tylenol.*, 2014 WL 3035791, at *3 (denying motion to quash the subpoenaed deposition of defendant's former President who “was actively involved in the decision making regarding...marketing and product development.”); *see also Otsuka Pharm. Co.*, 2008 WL 4424812, at *5 (denying defendant's motion for a protective order because the defendant's CEO had unique knowledge that other witnesses were unable to provide). When assessing whether the deposition of a high-ranking corporate officer is appropriate, Courts within the Third Circuit consider the following two factors: (1) whether the executive or top-level employee has personal or unique knowledge on relevant subject matters; and (2) whether the information sought can “be obtained from lower[-]level employees or through less burdensome means, such as interrogatories.” *Ford Motor Co. v. Edgewood Properties, Inc.*, 2011 WL 677331, at *2 (D.N.J. Feb. 15, 2011) (quoting *Reif v. CNA*, 248 F.R.D. at 451), *aff'd* 2011 WL 2517133 (D.N.J. June 23, 2011).

As discussed above, Dr. Rao was immersed in many core issues surrounding the contamination of Aurobindo's valsartan, the resulting recall, and interfacing with the FDA concerning these issues. Furthermore, because of Dr. Rao's extensive involvement, there is no lower-level person from whom this information can be obtained. Because he did much of this work himself and was the person to make final decisions on regulatory and recall-related issues,

he is in sole possession of the work product he created. Granted a protective order as to Dr. Rao would therefore be prejudicial to Plaintiffs.

C. Aurobindo Has Failed To Meet The Heavy Burden Required In Moving To Block A Deposition

A party seeking to block a deposition (or the production of a custodial file) bears the “heavy burden” of demonstrating that the discovery sought represents an undue burden. *Frank Brunckhorst Co. v. Ihm*, No. MISC. 12–0217, 2012 WL 5250399, at *4 (E.D. Pa. Oct. 23, 2012). Accordingly, “[i]t is rare for a court to issue a protective order that prohibits a deposition.” *U.S. v. Mariani*, 178 F.R.D. 447, 449 (M.D. Pa.1998); *See, e.g., Elsevier, Inc. v. Comprehensive Microfilm & Scanning Servs., Inc.*, No. 3:10–CV–02513, 2013 WL 5797639, at *3 (M.D. Pa. Oct.28, 2013) (“The federal courts clearly favor the taking of depositions and will prohibit their use only on a heightened showing of good cause.”).

Aurobindo argues that Dr. Rao’s discovery would be duplicative and overly burdensome. However, interestingly, Aurobindo provides no substance to back these claims up in its brief. Plaintiffs cannot respond to claims of burden without any facts to back that up. Merely asserting an objection with no factual support is not nearly enough to satisfy the “heavy burden” imposed by the Third Circuit regarding undue burden in relation to a motion for protective order. *See Ihm*, 2012 WL 5250399, at *4.

Because Aurobindo has failed to provide factual support for this objection, the Court should deny Aurobindo’s request for a Protective Order.

IV. CONCLUSION

Granting Aurobindo's Motion for Protective Order regarding Dr. Rao would prevent Plaintiffs from obtaining the necessary information about critical issues in this case. As discussed herein, Dr. Rao is not an apex witness, nor is he protected by the apex doctrine.

Accordingly, Plaintiffs respectfully request that the Court deny Aurobindo's Motion and allow this critically important discovery to proceed.

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Respectfully submitted,

/s/ Ruben Honik

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